

## REMARKS

Claims 17-19, 21-24, 26, 29 and 42-44 are under consideration in the present application. Claims 17-19, 21, 26, 29 and 42-44 are amended herein.

### Priority Claim

It is the Examiner's view that SEQ ID NOs:17 and 18, as claimed in the pending claims, are present only in priority application no. 09/579,536, now issued as U.S. Patent No. 6,716,974. With respect to SEQ ID NOs:17 and 18, Applicants have herein amended the priority claim of the pending claims in order to reflect that Applicants properly claim priority to U.S. Patent Application No. 09/579,536, now issued as U.S. Patent No. 6,716,974.

### Claim language

The Examiner has objected to claims 42 and 43 for recitation of the terms "angiogenic" and "differentiation effective amount." However, Applicants contend that the objected claim language is not deficient in any way, and is proper under USPTO rules for the following reasons.

Applicants respectfully remind the Examiner that Applicants are allowed to be their own lexicographers. See MPEP § 2106, which provides that:

However, an applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) and *Vitronics Corp. v. Conceptor Inc.*, 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996). Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings.").

Applicants have defined the terms recited by the Examiner, and therefore, the terms, as used in the claims, are proper. For example, from line 16 to line 22 on page 17 of the specification, Applicants repeatedly use the term "angiogenic" to refer to tissue that participates in the process of angiogenesis. At lines 10-15 on page 17, Applicants use the term "angiogenic effective

amount" to indicate an amount of a substance that indices the process of angiogenesis. Regarding the term "differentiation effective amount," the term is explicitly defined at lines 13-23 on page 21. Accordingly, Applicants' use of the terms recited by the Examiner is indeed proper.

Rejection of claims 17 and 18 under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 17 and 18 as allegedly being indefinite for recitation of the phrase "encoded by the nucleic acid sequence". While Applicants do not agree with the Examiner's reasoning, Applicants have nonetheless amended the claims, for the sake of expediting prosecution of the claims. Specifically, Applicants have amended claims 17 and 18 to recite, in part, "encoded by a nucleic acid sequence." Accordingly, Applicants submit that the Examiner's rejection has been overcome, and respectfully request reconsideration and withdrawal of the rejection.

Rejection of claims 17-19, 21 and 26 under 35 U.S.C. § 102(e)

Claims 17-19, 21 and 26 were rejected under 35 U.S.C. § 102(e) as being anticipated by Ish-Horowicz et al. (U.S. Patent No. 6,004,924; hereinafter "Ish-Horowicz"; applied to claim 26) and separately, by Sakano et al. (U.S. Patent No. 6,337,387; hereinafter "Sakano"; applied to claims 17-19, 21 and 26), and finally, by Li et al. (U.S. Patent No. 6,136,952; hereinafter "Li"). Applicants respectfully disagree for the following reasons.

The text of 35 U.S.C. § 102(e) sets forth that:

A person shall be entitled to a patent unless the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Applicants first address the rejection of claim 26 in view of the Ish-Horowicz patent. Applicants have amended claim 26 herein to recite that the composition comprises the Jagged polypeptide consisting of the sequence set forth in SEQ ID NO:18. Ish-Horowicz does not teach the Jagged polypeptide set forth in SEQ ID NO:18. Therefore, Ish-Horowicz does not

teach each and every element of Applicants' claimed invention, as is required for a reference to be a proper anticipatory reference under 35 U.S.C. § 102(e). Accordingly, Ish-Horowicz does not anticipate amended claim 26. Reconsideration and withdrawal of the Examiner's rejection of claim 26 pursuant to 35 U.S.C. § 102(e) is respectfully requested.

Regarding the rejection of claims 17-19, 21 and 26 in view of Sakano, Applicants submit that Sakano does not anticipate the claims for the following reasons. Claims 17-19, 21 and 26 recite nucleic acids encoding the polypeptide sequences set forth in the claims. The rejection is based on the Examiner's allegation that the cited patent discloses "the same" sequence found in SEQ ID NO:18 of the present application. However, Applicants have amended the claims herein.

As evidenced by the sequence alignment provided by the Examiner with the Office Action, the sequences in the Sakano patent differ from Applicants' claimed sequences (e.g., SEQ ID NO:18). In particular, Sakano teaches sequences which are longer than those currently claimed by Applicants. Therefore, Sakano does not teach each and every element of Applicants' claimed invention, as is required for a reference to be a proper anticipatory reference under 35 U.S.C. § 102(e). Accordingly, Sakano does not anticipate the amended claims. Reconsideration and withdrawal of the Examiner's rejection is respectfully requested.

Regarding the rejection of claims 17-19, 21-23, 26 and 29 in view of Li, Applicants submit that Li does not anticipate the claims for the following reasons. Claims 17-19, 21-23, 26 and 29 recite nucleic acids encoding the polypeptide sequences set forth in the claims. This rejection is also based on the Examiner's allegation that the cited patent discloses "the same" sequence found in SEQ ID NO:18 of the present application.

Again, as evidenced by the sequence alignment provided by the Examiner with the Office Action, the sequences in the Li patent differ from Applicants' claimed sequences (e.g., SEQ ID NO:18). In particular, Li also teaches sequences which are longer than those currently claimed by Applicants. Li does not teach the exact sequences claimed in the present invention. Therefore, Li does not teach each and every element of Applicants' claimed invention, as is required for a reference to be a proper anticipatory reference under 35 U.S.C. § 102(e). Accordingly, Li does not anticipate the amended claims. Reconsideration and withdrawal of the Examiner's rejection is respectfully requested.

Rejection of claims 22-24 and 42-44 under 35 U.S.C. 103(a)

The Examiner has rejected claims 22-24 as being unpatentable over Sakano, in view of Neri et al. (U.S. Patent No. 6,117,976; hereinafter, "Neri"), and separately, has rejected claims 24 and 42-44 as being unpatentable over Li in view of Neri. Applicants respectfully traverse both rejections, and respectfully submit that the combination of art cited by the Examiner does not render the claims obvious under 35 U.S.C. § 103(a) for the following reasons.

As a preliminary matter, Applicants note that the Examiner has described the rejections in view of Sakano and Neri, and in view of Li and Neri, as being rejected under "35 U.S.C. § 102(e)". While Applicants presume that this is a typographical error, Applicants nonetheless reassert the arguments set forth above as to why Sakano and Li do not anticipate the claimed invention.

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103... [T]he four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. MPEP § 2141.

Additionally, MPEP § 2143.01 provides: "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)." (emphasis added).

None of these criteria have been met here.

The Examiner's first rejection is based on the allegation that the cited patent discloses "the same" sequence found in SEQ ID NO:18 of the present application. However, Applicants have amended the claims herein. Specifically, claims 22-24 are now directed to an isolated polypeptide encoded by a nucleic acid sequence consisting of the sequence from nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2

As set forth above, Applicants' claims are drawn to unique nucleic acids encoding

the polypeptide sequences set forth in the claims. Neither Sakano nor Neri teaches the exact claimed sequence. As evidenced by the sequence alignment provided by the Examiner with the Office Action, the sequences in the Sakano patent differ from Applicants' claimed sequences (e.g., SEQ ID NO:18). In particular, Sakano teaches sequences which are longer than those currently claimed by Applicants. Therefore, Sakano does not teach Applicants' claimed invention.

Sakano teaches only a longer sequence than that claimed by Applicants, and Sakano does not provide any suggestion or motivation to the skilled artisan as to why one would specifically prepare a polypeptide based on the limited sequence from nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2. Such information was provided for the first time only in Applicants' own disclosure. To rely on such information to support an obviousness rejection would constitute improper hindsight reasoning.

The Neri reference does not cure this deficiency, as Neri teaches only various protein tags, which are not even related to Jagged proteins. Moreover, there is no teaching or suggestion in Neri of the nucleic acid or amino acid residues that must be deleted in the Sakano sequence in order to arrive at Applicants' claimed sequence.

Because neither Sakano nor Neri discloses Applicants' presently-claimed sequence, and because neither reference provides any motivation or suggestion to arrive at Applicants' presently-claimed sequence, Sakano and Neri, when taken together, do not provide any suggestion or motivation to the skilled artisan to arrive at Applicants' presently-claimed invention. Furthermore, because Sakano and Neri, when taken together, do not provide any suggestion or motivation to the skilled artisan to arrive at Applicants' presently-claimed invention, the skilled artisan would not have any reasonable expectation of success in arriving at the invention set forth in claims 22-24.

For the reasons discussed above, the combination of Sakano and Neri does not render claims 22-24 obvious under 35 U.S.C. § 103(a) and, therefore, the rejection should be reconsidered and withdrawn.

The Examiner's second obviousness-based rejection is also based on the allegation that the cited patent discloses "the same" sequence found in SEQ ID NO:18 of the present application. However, as set forth above, Applicants' amended claims are drawn to unique nucleic acids encoding the polypeptide sequences set forth in the claims. Neither Li nor

Neri teaches the exact claimed sequence. As evidenced by the sequence alignment provided by the Examiner with the Office Action, the sequences in the Li patent differ from Applicants' claimed sequences (e.g., SEQ ID NO:18). In particular, Li teaches sequences which are longer than those currently claimed by Applicants. Therefore, Li does not teach Applicants' claimed invention.

Like Sakano, Li teaches only a longer sequence than that claimed by Applicants, and Li does not provide any suggestion or motivation to the skilled artisan as to why one would specifically prepare a polypeptide based on the limited sequence from nucleotide number 1 to nucleotide number 3201 of SEQ ID NO:2. Such information was provided for the first time only in Applicants' own disclosure. To rely on such information to support an obviousness rejection would constitute improper hindsight reasoning.

The Neri reference does not cure the deficiency of Li, as Neri teaches only various protein tags, which are not even related to Jagged proteins. Moreover, there is no teaching or suggestion in Neri of the nucleic acid or amino acid residues that must be deleted in the Li sequence in order to arrive at Applicants' claimed sequence.

Because neither Li nor Neri discloses Applicants' presently-claimed sequence, and because neither reference provides any motivation or suggestion to arrive at Applicants' presently-claimed sequence, Li and Neri, when taken together, do not provide any suggestion or motivation to the skilled artisan to arrive at Applicants' presently-claimed invention. Furthermore, because Li and Neri, when taken together, do not provide any suggestion or motivation to the skilled artisan to arrive at Applicants' presently-claimed invention, the skilled artisan would not have any reasonable expectation of success in arriving at the invention set forth in claims 24 and 42-44.

For the reasons discussed above, the combination of Li and Neri does not render claims 24 and 42-44 obvious under 35 U.S.C. § 103(a) and, therefore, the rejection should be reconsidered and withdrawn.

Summary

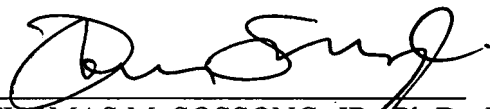
Applicants respectfully submit that the amendments made to the claims and the specification herein do not introduce new matter, and that the arguments set forth herein evidence that the pending claims are in full condition for allowance. Accordingly, favorable examination of the claims is respectfully requested at the earliest possible time.

Respectfully submitted,

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24-APR-2007

Date



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